IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant	:	Sirimanne
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Group Art Unit:		3737
Examiner	:	Smith, Ruth S.
Docket No.	:	END-5247USCNT1
Customer No.:		021884
Title	:	SUBCUTANEOUS CAVITY MARKING DEVICE AND METHOD

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner of Patents and Trademarks
PO Box 1450
Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

Ethicon Endo-Surgery, Inc. is the real party in interest in the above referenced patent application.

RELATED APPEALS AND INTERFERENCES

Appellants' representative, Appellants' assignee, and Appellants are unaware of any related appeals and/or interferences affected by or having a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111-123 are currently pending. Claims 1-7, 16, 17, 22-24, 31, 33, 111, 122 and 123 stand finally rejected. Claims 8-15, 18-21, 25-30, 32 and 35-110 have been canceled. Claims 112-121 have been withdrawn. Appellants accordingly appeal the final rejection of claims 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 and 123.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Rejection. As to the amendments filed prior to the Final Rejection, all amendments appear to have been entered and considered.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 is at issue in the present Appeal and is, therefore, summarized below. Dependent claims 2, 5, 16, 17, 22, 23, 24, 31, and 123 are argued separately and, therefore, summarized below.

Independent claim 1 sets forth a subcutaneous cavity marking device 100 percutaneously implantable in breast tissue during a biopsy procedure. Specification, Paragraph [0047]. The device comprises at least two implantable bodies, for example, bodies 302, 326. Specification, Paragraph [0047-0050]. One of the implantable bodies is made from a first material and the other implantable body is made from a second material. Specification, Paragraph [0056-0057 and 0060-0061]. The first material and second materials are different materials. Specification, Paragraph [0056-0057 and 0060-0061]. The at least two implantable bodies are adapted to be inserted into a subcutaneous cavity created by removal of tissue. Specification, Paragraph [0071]. The at least two implantable bodies are detectable as tissue cavity markers via non-invasive techniques. Specification, Paragraph [0057 and 0062]. Further, one of the at least two detectable bodies is disposed within the other of the at least two implantable bodies, and the other of the at least two implantable bodies is bioabsorbable. Specification, Paragraph [0055-0056].

Claim 2 depends from claim 1 and sets forth that at least one of the at least two detectable bodies comprises a non-bioabsorbable material forming a permanent marker. Specification, Paragraph [0055].

Claim 5 depends from claim 4, which depends from claim 1, and sets forth that the bioabsorbable material comprises a polymer having a radiopaque additive. Specification, Paragraph [0061].

Claim 16 depends from claim 1 and sets forth the addition of a pain killing substance to the subcutaneous cavity marking device. Specification, Paragraph [0070].

Claim 17 depends from claim 1 and sets forth the addition of a hemostatic substance to the subcutaneous cavity marking device. Specification, Paragraph [0070].

Claim 22 depends from claim 1 and sets forth that the other of the at least two implantable bodies comprises a suture 326 in a pattern which crosses. Specification, Paragraph [0067].

Claim 23 depends from claim 1 and sets forth that the other of the at least two implantable bodies comprises a wire 326 in a pattern which crosses. Specification, Paragraph [0067].

Claim 24 depends from claim 1 and sets forth that one of the at least two implantable bodies is detectable via ultrasound and has a distinguishing pattern. Specification, Paragraph [0059].

Claim 31 depends from claim 1 and sets forth that the at least two implantable bodies have a substantially irregular shape 106. Specification, Paragraph [0047].

Claim 123 depends from claim 1 and sets forth that one of the at least two implantable bodies is formed in a cross pattern 326 to mark a particular section of the cavity. Specification, Paragraph [0065 and 0067].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 and 123 stand properly rejected under 35 U.S.C. § 112, first paragraph.
2. Whether claims 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 and 123 stand properly rejected under 35 U.S.C. § 112, second paragraph.
3. Whether claims 1-7, 16, 31, 33, 34, 111 and 122 stand properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0012652 to Levy et al. ("Levy") in view of U.S. Patent No. 6,197,324 to Crittenden ("Crittenden").
4. Whether claim 17 stands properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy in view of Crittenden, and further in view of U.S. Patent No. 6,666,811 to Good ("Good").
5. Whether claims 22, 23 and 123 stand properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy in view of Crittenden, and further in view of U.S. Patent No. 5,632,775 to Suding et al. ("Suding") or U.S. Patent No. 4,985,019 to Michelson ("Michelson").
6. Whether claim 24 stands properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy in view of Crittenden, and further in view of U.S. Patent No. 6,106,473 to Violante et al. ("Violante") and Suding or Michelson.

ARGUMENTS

I. CLAIMS 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 AND 123 ARE NOT PROPERLY REJECTED UNDER 35 U.S.C. § 112, FIRST PARAGRAPH.

The claims have been rejected for failing to comply with the written description requirement. The Examiner suggests the claims include subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. More specifically, the Examiner suggests the specification fails to disclose a cavity marking device having at least two bodies made from different materials which are each detectable by non-invasive techniques.

With regard to this rejection, the subject matter of the claims is fully supported by the specification as originally filed. Appellants have chosen to use the term "implantable bodies" to broadly encompass both a body and a marker as both are components of the subcutaneous cavity marking device which is implanted during use. The specification clearly discloses the use of two implantable bodies together. See, Specification, Paragraph [0047-0050]. Based upon this disclosure, one of ordinary skill in the art would surely comprehend how to make a subcutaneous cavity marking device from two different implantable bodies used together based upon the disclosure presented in Appellants' specification. Further, the specification makes it clear the materials used for the body and marker can be different and detectable by non-invasive techniques, see page 14, lines 10-14, of the specification as originally filed, which disclose the body being located via non-invasive techniques and paragraph [0060] of the specification as originally filed which discloses the marker being located via non-invasive techniques.

Since the specification fully supports that which has been claimed, this rejection under § 112, first paragraph, is believed to be improper and Appellants respectfully request that it be reversed.

II. CLAIMS 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 AND 123 ARE NOT PROPERLY REJECTED UNDER 35 U.S.C. § 112, SECOND PARAGRAPH.

The Examiner suggests claims 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 and 123 are indefinite. More particularly, the Examiner suggests the claims fail to set forth any structural limitation that would provide for the implantable bodies to be detectable via non-invasive techniques. However, just because a claim is broad does not mean it is indefinite.

In the claim-at-issue, the language "detectable via non-invasive techniques as tissue cavity markers" is a physical characteristic of the implantable bodies and not merely functional language. Claiming a physical characteristic of a claimed element is entirely proper and entitled to full patentable weight upon examination. Such language may be used to further limit a claim so long as the physical characteristic is definable to one of ordinary skill in the art. With reference to the claim limitation at hand, one skilled in the art would certainly understand the meaning of "detectable via non-invasive techniques" when one considers the ordinary and customary meaning of the term and the fact the specification clearly sets forth various non-invasive techniques. See Specification, Paragraph [0057 and 0062].

Since the claims are definite as discussed above, the § 112, second paragraph, rejection is believed to be improper and Appellants respectfully request it be reversed.

III. CLAIMS 1-7, 16, 31, 33, 34, 111 AND 122 ARE PATENTABLE OVER LEVY IN VIEW OF CRITTENDEN

Claims 1-7, 16, 31, 33, 34, 111 and 122 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy in view of Crittenden. This rejection is improper and Appellants respectfully request reversal thereof.

Claim 1 is the sole independent claim and requires a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure. The device comprises at least two implantable bodies. One of the implantable bodies is made from a first material and the other implantable body is made from a second material. The first material and second materials are different materials. The at least two implantable bodies are adapted to be inserted into a subcutaneous cavity created by removal of tissue. The at least two implantable bodies are detectable as tissue cavity markers via non-invasive techniques. Further, one of the at least two detectable bodies is disposed within the other of the at least two implantable bodies, and the other of the at least two implantable bodies is bioabsorbable.

As such, all of the claims of the present application require a subcutaneous cavity marking device. However, not one of the cited references is directed to a subcutaneous cavity marking device. Therefore, it is not clear how the combination of cited references, not one of which discloses a critical limitation of the claimed invention, can render something they fail to teach to be obvious.

Contrary to the Examiner's opinion, the preamble of a claim cannot be summarily dismissed and given no weight. The language "a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure" is not purely

functional but very specifically defines the claimed invention. While "percutaneously implantable in breast tissue during a biopsy procedure" may be a functional recitation, "a subcutaneous cavity marking device" is a well defined structure. The outstanding rejections are based upon obviousness and the combination of references relied upon must at a minimum define a subcutaneous cavity marking device. Just because structures exists which can be used in the body does make such structure a subcutaneous cavity marking device; considering the present claims, not all intracorporeal medical devices may be implanted into a cavity in a body created when a biopsy is taken in order to result in a subcutaneous cavity marking device.

Whether to treat a preamble as a limitation is a determination "resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). In general, a preamble limits the claimed invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Catalina Mktg., 289 F.3d at 808, 62 USPQ2d at 1784 (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

Both the specification and prosecution history of the present application make clear that the phrase "subcutaneous cavity marking device" defines the claimed invention giving it life, meaning and vitality, and is, therefore, a limitation of the claims. The preamble requires "[a] subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure" and the pertinent case law holds that the preamble is given full weight if it

breathes life and meaning into the claim. Without the preamble of the present claim, it has no true meaning and the preamble is necessary in appreciating the invention being claimed. In contrast, the Examiner ignores the preamble and would have one believe Appellants have attempted to claim any two bodies insertable into the human body. Considering, for example, a prosthetic device, a prosthetic can be formed from two different components or bodies, but it surely cannot be transformed into a subcutaneous cavity marking device as defined by Appellants' specification and claims.

Applying this to Levy, the microspheres disclosed by Levy might have a diameter of about 1 to 900 μm and are used in gene therapy, but they are not suitable for use as subcutaneous cavity marking devices. Still further, they do not, and could not, result in a subcutaneous cavity marking device.

Accordingly, the primary reference of Levy does not anticipate or render obvious the claims because Levy fails to disclose or suggest a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure. Further with regard to the prior art rejections, there is no reason one of ordinary skill in the art would modify Levy with the teachings of Crittenden. Even if so modified, a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure does not result.

Levy teaches very small microspheres containing condensed polyanionic bioactive agents, such as DNA, and a method for their production. The microspheres may be incorporated into a matrix for release in the body, but this does not turn a gene therapy drug delivery system into a subcutaneous cavity marking device. Regardless of how the Examiner suggests modifying Levy based upon the disclosure of Crittenden, the end result is not a

subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure. The best case result of any modification being suggested by the Examiner is a device including bioactive microspheres used for sustained drug delivery to transfer genes to targeted cells.

The claims further require that the at least two implantable bodies are detectable as tissue cavity markers via non-invasive techniques. The Examiner has incorrectly interpreted Levy regarding facilitating visualization. Levy's only disclosure relating to visualization can be found in paragraph [0055], which is reproduced below.

> The present invention is useful for preparations of a wide variety of polyanionic bioactive agents. The agents described infra primarily exert their bioactive effect by causing direct changes to the cell. However, the term "bioactive" as used in this Application is intended to include any substance that interacts with biological elements. Thus, bioactive agents include substances such as dyes or labeling proteins whose primary use is to facilitate identification or visualization of biological structures or functions.

Based upon this disclosure, Levy only discloses microspheres containing a bioactive agent which affects and causes direct changes to cells in the body so that the bioactive agent may interact with the targeted cells so that the cells can be identified or visualized. Releasing microspheres containing a bioactive agent to identify and visualize cells has nothing to do with marking a subcutaneous cavity. Levy is not concerned with identifying or visualizing the microspheres or the matrix into which they may be delivered. While it may be possible the matrix with microspheres of Levy could be placed into a subcutaneous cavity, the microspheres would be released and would still need to interact with cells if visualization is to occur. Since a cavity would be void of cells, visualization or marking of the cavity would not

occur. Thus, it is impossible for Levy to perform the function of a subcutaneous cavity marking device. There is no disclosure in Levy as to using the microspheres/matrix combination as markers of any type and this deficiency is not overcome by Crittenden.

Crittenden is relied upon to teach "the use of a radiopaque marker in a pellet in order to show that its location can be properly determined". Based upon this disclosure alone the Examiner would have us believe it becomes obvious to modify both the matrix and microspheres of Levy to include radiopaque markers so as to be locatable by X-ray.

What Crittenden really teaches is temporarily implanting pellets containing local anesthetic agents into myocardial tissue. Crittenden briefly mentions that the pellets may include a radio-opaque marker at their core. To quote Crittenden, "[i]n a further aspect, the invention can be understood as pellets adapted for carrying a therapeutic agent into the tissue wall of a patient. In one embodiment, the pellets include a radio-opaque marker typically located at the core of the pellet which facilitates the fluoroscopic viewing of the delivery of the pellets".

So once again Crittenden, like Levy, fails to teach a subcutaneous cavity marking device and only teaches fluoroscopic viewing during the delivery of the pellets. There is no disclosure in Crittenden regarding marking any type of cavity or a desire to mark tissue. Crittenden only includes a marker so that viewing can occur during delivery to make sure the pellet is implanted in the tissue desired to be treated. From this limited disclosure the Examiner arrives at the conclusion it is somehow obvious to modify Levy to create Appellants' invention.

The mere motivation of including radiopaque markers in pellets so that the pellets can be seen during delivery to ensure proper placement in myocardial tissue does not provide a reasonable rationale as to including markers in the microspheres and matrix of Levy and converting Levy from a gene therapy system into a subcutaneous cavity marking device. In fact, this is not a proper motivation at all as Levy is not concerned with the location of his microspheres before, during or after release into the body. The microspheres release bioactive agents which then target cells and the cells may be visualized, but there is no need in Levy to visualize the microspheres.

Based upon the Examiner's logic, it appears that because Crittenden teaches the use of a radiopaque marker in a pellet it becomes obvious to modify anything placed in the human body and turn it into a subcutaneous cavity marking device percutaneously implantable during a biopsy procedure. Such a rationale is not proper and a rationale as to why one would employ Levy to mark a subcutaneous cavity is clearly lacking. Additionally, how and why Levy could be used to mark a subcutaneous cavity is lacking. Appellants are concerned with marking a subcutaneous cavity and not identifying and visualizing cells wherever they are found in a body. One of ordinary skill understands these are two different things.

Again returning to the prosthetic analogy, just because a prosthetic exists does not mean it can be used as a subcutaneous cavity marking device if radiopaque markers are added to the prosthetic. There is no one in the medical field that would intentionally use a microsphere containing a bioactive agent or a prosthetic during a biopsy to mark a cavity. A matrix including microspheres which contain a bioactive substance as disclosed by Levy would not, and could not, effectively be used as a subcutaneous cavity marking device

percutaneously implanted in breast tissue during a biopsy procedure. Ultimately, Levy's structure must minimally be able to function as a subcutaneous cavity marking device, and it simply does not remotely resemble a subcutaneous cavity marking device.

Quite simply, Levy cannot mark a cavity if its intended propose is to identify and visualize cells because there are no cells in a cavity. Thus, regardless of how Levy is modified, its intended purpose cannot be changed. Whatever Levy discloses as the use for his invention cannot be simply changed by modifying it with a teaching from Crittenden, especially when Crittenden also fails to teach the claimed device. Therefore, whatever Crittenden teaches it cannot overcome the deficiencies of Levy.

Further, and with reference to claim 2, the subcutaneous cavity marking device requires that one of the two detectable bodies comprise a non-bioabsorbable material forming a permanent marker. This limitation is not addressed in the Office Action and both Levy and Crittenden fail to teach such structure. Levy teaches no markers and Crittenden teaches the desire to only have temporary markers.

With regard to Claim 5, this claim requires that the body of the subcutaneous cavity marking device made from a bioabsorbable material be comprised of a polymer having a radiopaque additive. This limitation is not addressed in the Office Action and both Levy and Crittenden fail to teach such structure. Levy teaches no portion of his device is made from a polymer having a radiopaque additive and Crittenden only teaches adding a radiopaque marker to a pellet which is not a teaching of a polymer having a radiopaque additive being added to a pellet or a microsphere.

Claim 16, while addressed in the Office Action, requires the addition of a pain killing substance to the subcutaneous cavity marking device. However, merely because the use of pain killing substances is known to be used during medical produces does not provide a rationale as to why Levy would add such a substance to his microspheres. Specifically, why would Levy be concerned with addressing pain when there is no disclosure in Levy that the delivery of his microspheres caused pain?

Claim 31 requires the two implantable bodies forming the subcutaneous cavity marking device have a substantially irregular shape. This limitation has been dismissed as a matter of design choice. Levy clearly indicates his invention is in the form of microspheres and gives diameter ranges. Contrary to Levy's own disclosure, the Examiner considers it obvious to change the shape of microspheres to something other than disclosed by Levy because the Examiner feels shape is just a matter of design choice. Merely being a matter of design choice is not a sustainable rationale when it contradicted by the applied reference's own disclosure.

Since the rejection of claims 1-7, 16, 31, 33, 34, 111 and 122 has been shown to be improper it is respectfully requested that the rejection be reversed.

IV. CLAIM 17 IS PATENTABLE OVER LEVY IN VIEW OF CRITTENDEN AND GOOD

The subcutaneous cavity marking device set forth in claim 17 requires a hemostatic substance. Hemostatic substances are used to stop bleeding and bleeding generally occurs when tissue is removed during a subcutaneous biopsy. There is nothing in Levy which indicates his microspheres are implanted. Even assuming they are implanted, there is no

indication the site at which they are implanted requires or would benefit from hemostasis. Thus, to add a hemostatic substance to Levy just because Good teaches implantable bodies can include hemostatic material is not a rationale supported by the references. It is merely an unsupported conclusion and appears to be based upon impermissible hindsight and a desire to manufacture a rejection when the prior art does not support such a rejection.

Since the rejection of claim 17 has been shown to be improper it is respectfully requested that the rejection be reversed.

V. CLAIMS 22, 23 AND 123 ARE PATENTABLE OVER LEVY IN VIEW OF CRITTENDEN, SUDING AND MICHELSON

These claims all require that one of the two implantable bodies is formed in a cross pattern to mark a section of a cavity. However, the Examiner has failed to set forth any reference showing a cross pattern to mark a section of a cavity. Additionally, claim 22 requires the cross be formed with a suture, claim 23 requires the cross be formed with wire and claim 123 requires the cross be formed so as to mark a particular section of the cavity.

Again, it appears the Examiner believes that just because she has uncovered references which teach forming radiopaque patterns it becomes obvious to form cross patterns in a subcutaneous cavity marking device as claimed by Appellants. The mere fact that things are known is not proper motivation to combine references. The patent laws require a little more than the mere fact structure exist to make it combinable with another reference. In the case at hand, it is hard to understand how micron sized microspheres could be manufactured such that a cross pattern formed from a suture or wire could be viewed by x-ray and how this tiny cross pattern would ensure proper placement in a patient, all based upon the teachings of

Suding and/or Michelson. Suding teaches a flange on a voice prosthesis formed with a distinctive radiopaque pattern. Michelson teaches x-ray markers which are adhesively applied to a patient's skin for use in determining the location of where a needle is to be placed.

The mere fact radiopaque patterns exist on a voice prosthesis or a skin marking sticker does not make them obvious to include in drugs being delivered to a patient. A logical rationale as to why one would modify Levy needs to be set forth. Since Levy is not concerned with the placement of his microspheres, there is no reason to turn to Suding and/or Michelson especially when neither have anything to do with placement of microspheres within a body.

Since the rejection of claims 22, 23 and 123 has been shown to be improper it is respectfully requested that the rejection be reversed.

VI. CLAIM 24 IS PATENTABLE OVER LEVY IN VIEW OF CRITTENDEN, VIOLANTE, SUDING AND MICHELSON

The subcutaneous cavity marking device set forth in claim 24 requires one of the two implantable bodies is detectable via ultrasound and has a distinguishing pattern. Somehow the Examiner arrives at the conclusion that because Violante teaches echogenic coatings can be applied to pellets or implants, it becomes obvious to modify the micron sized gene therapy microspheres of Levy with a coating. Further, this coating is going to be applied in a particular pattern because Suding and Michelson disclose the use of detectable patterns.

Regardless of what a reference teaches there must be some motivation to combine them and the motivation needs to come from the references. While Suding and Michelson

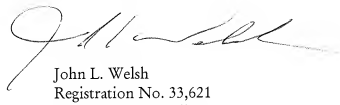
teach detectable patterns, they don't teach forming them in echogenic coatings. While Violante teaches echogenic coatings, he fails to teach applying such coatings to micron sized gene therapy microspheres. Since Levy fails to disclose a desire to mark his microspheres, this deficiency needs to be found in the other references applied in creating a rejection. Violante, Suding and/or Michelson taken alone or in combination fail to overcome the deficiency of Levy and provide no rationale as to why Levy would coat his microspheres with echogenic material in a particular pattern.

Since the rejection of claim 24 has been shown to be improper it is respectfully requested that the rejection be reversed.

VII. CONCLUSION

In conclusion, Appellants have now shown that the references cited by the Examiner neither disclose nor suggest the claimed invention. Therefore, it is respectfully requested that the outstanding rejection of claims 1-7, 16, 17, 22-24, 31, 33, 34, 111, 122 and 123 be reversed.

Respectfully submitted,



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CLAIMS APPENDIX

1. A subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure comprising:

at least two implantable bodies, one made from a first material and another made from a second material wherein the first and second materials are different materials and the at least two implantable bodies are adapted to be inserted into a subcutaneous cavity created by removal of tissue, wherein the at least two implantable bodies are detectable via non-invasive techniques as tissue cavity markers; and

at least one of the at least two detectable bodies is disposed within the other of the at least two implantable bodies wherein the other of the at least two implantable bodies is bioabsorbable.

2. The device of claim 1 wherein the at least one of the at least two detectable bodies comprises a non-bioabsorbable material forming a permanent marker.

3. The device of claim 2 wherein the permanent marker comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof and stainless steel.

4. The device of claim 1 wherein the at least one of the at least two detectable bodies comprises a bioabsorbable material.

5. The device of claim 4 wherein the bioabsorbable material comprises a polymer having a radiopaque additive.

6. The device of claim 5 wherein the radiopaque additive is selected from the group consisting of barium-containing compounds, bismuth-containing compounds, powdered tantalum, powdered tungsten, barium carbonate, bismuth oxide, and barium sulfate.

7. The device of claim 1 wherein the at least one of the at least two detectable bodies is radiopaque.

16. The device of claim 1 additionally comprising a pain killing substance.

17. The device of claim 1 additionally comprising a hemostatic substance.

22. The device of claim 1 wherein the other of the at least two implantable bodies comprises a suture in a pattern which crosses.

23. The device of claim 1 wherein the other of the at least two implantable bodies comprises a wire in a pattern which crosses.

24. The device of claim 1 wherein one of the at least two implantable bodies is detectable via ultrasound and has a distinguishing pattern.

31. The device of claim 1 wherein the at least two implantable bodies have a substantially irregular shape.

33. The device of claim 1 wherein the at least two implantable bodies have a plurality of pores.

34. The device of claim 33 wherein the pores are configured to promote tissue growth in a preferred orientation.

111. The device of claim 1 wherein one of the at least two implantable bodies is made from an expandable material.

112. (Withdrawn) A subcutaneous cavity marking assembly comprising: (a) an outer component comprising a bioabsorbable material; (b) an inner component enclosed by the outer component, the inner component comprising a radiopaque marker element; and (c) a needle enclosing the inner and outer components.

113. (Withdrawn) The device of claim 112 wherein the inner component comprises a nonabsorbable marker element.

114. (Withdrawn) The device of claim 112 wherein the inner component comprises a metallic marker element.

115. (Withdrawn) The device of claim 112 wherein the inner component comprises a titanium marker element.

116. (Withdrawn) The device of claim 112 wherein the outer component is resilient and self expands upon being disposed in a biopsy cavity.

117. (Withdrawn) The device of claim 112 wherein the outer component comprises a plurality of pores or openings.

118. (Withdrawn) The device of claim 112 wherein the outer component comprises a bioabsorbable polymer.

119. (Withdrawn) The device of claim 112 wherein the outer component comprises a suture or suture-like material.

120. (Withdrawn) A biopsy cavity marking assembly comprising:

an access tube;

a biopsy cavity marking device disposed within the access tube, the biopsy cavity marking device comprising:

a compressed, resilient bioabsorbable outer body having a plurality of openings; and

a metallic marker enclosed within the outer body.

121. (Withdrawn) The biopsy cavity marker assembly of claim 120 wherein the outer body self expands upon exiting the access tube.

122. The device of claim 1 wherein one of the at least two implantable bodies has a plurality of pores.

123. The device of claim 1 wherein one of the at least two implantable bodies is formed in a cross pattern to mark a particular section of said cavity.

EVIDENCE APPENDIX

Not Applicable

RELATED PROCEEDINGS APPENDIX

Not Applicable